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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,827

Applicant(s)

BENFEY ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-25, 27 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-25, 27 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 25, 2003 has been entered.

Claims 1-21, 26, 28-30 and 32-33 are cancelled.

Claims 22, 24, 27 and 31 are currently amended.

Claims 22-25, 27 and 31 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-25, 27 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

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claimed invention. This is a new matter rejection. The claims are directed to a promoter “consisting essentially of” a nucleic acid sequence of SEQ ID NO:4, and transgenic plants comprising said promoter. The limitation “consisting essentially of” does not find support in the specification as originally filed, and thus constitutes new matter.

Claims 22-25, 27 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are directed to a promoter “consisting essentially of” a nucleic acid sequence of SEQ ID NO:4 and functioning to promote stele-specific expression in roots, shoots and embryos of a plant, and transgenic plants comprising said promoter.

The specification describes a single 2502 base pair promoter sequence of SEQ ID NO:4 obtained from the *SHORT-ROOT* gene of *Arabidopsis* that functions to promote expression a GFP reporter gene in the stele of roots and hypocotyls, and in the stele and procambrium of embryos and cotyledons (sequence listing; pages 66-67 and *Figures 3 and 4*). The specification does not describe or characterize other promoter sequences, or the specific nucleotides or nucleotide sequence motifs of SEQ ID NO:4 that are associated with the ability of SEQ ID NO:4 to promote stele-specific expression of a sequence operatively associated therewith.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that “A description of a genus of cDNAs may be achieved by

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means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case Applicant has not described a representative number of species falling within the scope of the genus “promoters consisting essentially of a nucleic acid sequence of SEQ ID NO:4 that function to promote stele-specific expression in roots, shoots and embryos of a plant”, nor the structural features unique to this genus.

Claims 27 remains rejected, and claims 22-25 and 31 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising a nucleic acid sequence of SEQ ID NO:4, and a transgenic plant comprising said promoter operatively associated with a gene of interest, including a *SHORT-ROOT* gene, does not reasonably provide enablement for a promoter consisting essentially of a nucleic acid sequence of SEQ ID NO:4, or for a transgenic plant comprising said promoter operatively associated with a gene of interest, for the reasons of record set forth below.

Applicant's arguments filed November 25, 2003 in response to the previous rejection of claims 27 and 32-33 have been fully considered, but they are not persuasive with respect to the current rejection of claims 22-25, 27 and 31.

Applicant argues that the rejection should be withdrawn in light of the cancellation of claims 32 and 32, and in light of the amendment of claim 27 to depend from claim 22 and to

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recite that the gene of interest is a *SHORT-ROOT* gene, which gene of interest finds support in the specification at pages 12-13 and 48-49. (reply page 3)

With respect to the amendment of claim 27, the scope of enablement rejection has been adjusted accordingly, since the claim now recites only that the *SHORT-ROOT* gene is the gene of interest operatively associated with the claimed promoter sequence. However, the rejection is maintained and extended to claims 22-25 and 31 for the reasons set forth below.

The pending claims are directed to a promoter “consisting essentially of” a nucleic acid sequence of SEQ ID NO:4 and functioning to promote stele-specific expression in roots, shoots and embryos of a plant, and transgenic plants comprising said promoter.

The specification discloses a promoter of SEQ ID NO:4 obtained from the *SHORT-ROOT* gene of *Arabidopsis* that functions to promote expression a GFP reporter gene in the stele of roots and hypocotyls, and in the stele and procambrium of embryos and cotyledons (pages 66-67 and *Figures 3 and 4*). The specification does not disclose the specific nucleotides or nucleotide sequence motifs of SEQ ID NO:4 that are associated with its promoter function, or that are associated with the ability of SEQ ID NO:4 to promote stele-specific expression of a sequence operatively associated therewith.

Guidance for making and using the claimed invention is necessary for enablement because it is unpredictable what type of changes would materially affect the basic and novel characteristics of a nucleic acid sequence of SEQ ID NO:4 and what type would not. It is unpredictable because promoter function is mediated by the direct interaction between proteins and specific nucleotides within the promoter that may vary between different promoter sequences. See, for example, the original rejection of claims 22-25, 27 and 30-33 under 35 USC

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112, first paragraph, at Pages 5-6 of the office action Mailed January 3, 2002. In the instant case the specific nucleotides of SEQ ID NO:4 that mediate promoter function are not disclosed.

It is also unpredictable because tissue-specific promoter function is mediated by the direct interaction between proteins and specific nucleotide sequence motifs within the promoter that may vary between different promoter sequences. See, for example, Fiedler et al. (Plant Molecular Biology, 1993, Vol. 22, pages 669-679), who teach that the basic promoter region directs seed-specific gene expression from the *Vicia faba* non-storage seed protein gene promoter, whereas sequences further upstream of the basic promoter region are required to direct seed-specific gene expression from the legumin B4 gene promoter (page 677 column 1 fourth full paragraph). Fiedler et al. also teach that an RY motif "CATGCATG" acts as a negative transcriptional regulatory element in the seed-specific promoter of the *Vicia faba* non-storage seed protein gene, and as a positive transcriptional regulatory element in seed-specific promoters obtained from other plant structural genes (page 677 paragraph spanning columns 1 and 2). In the instant case the specific nucleotide sequence motifs of SEQ ID NO:4 that mediate stele-specific expression in roots, shoots and embryos of a plant are not disclosed.

Absent guidance with respect to what type of changes would materially affect the basic and novel characteristics of a nucleic acid sequence of SEQ ID NO:4 and what type would not, it would require undue experimentation for one skilled in the art to determine how to change SEQ ID NO:4 in such a way that the resultant sequence would promote stele-specific expression in roots, shoots and embryos of a plant transformed therewith, as every type of change made to SEQ ID NO:4 would have to be constructed and tested for its ability to function as claimed.

Claim Rejections - 35 USC § 102

Claim 31 remains rejected under 35 U.S.C. 102(b) as being anticipated by Bevan et al. (GenBank Accession No. AL035605, March 4, 1999), for the reasons of record set forth in the office action mailed September 27, 2002.

Applicant's arguments filed November 25, 2003, have been fully considered but they are not persuasive.

Applicant argues that Bevan et al. is not an enabling reference because Bevan et al. do not identify the starting and ending positions of the nucleotide sequence of SEQ ID:4 contained within the BAC clone F19F18, and because, unlike other nucleotide sequences contained within the BAC clone F19F18, Bevan et al. do not single out the nucleotide sequence of SEQ ID:4 as having any particular function. (reply pages 5-6)

The Office maintains that the sequence taught by Bevan et al. anticipates the claimed invention. Bevan et al. need not identify the starting and ending positions of the nucleotide sequence of SEQ ID:4, or single out the nucleotide sequence of SEQ ID:4 as having any particular function, in order to be enabled. See, for example, *Titanium Metals Corp. of America v. Banner* 227 USPQ 775, recitation of a heretofore unknown inherent property of a known composition does not impart novelty to that composition. See also, for example, *In re Schoenwald* 22 PQ2d 1671, a disclosure that fails to teach how to use a fully disclosed compound is entirely adequate to anticipate a claim to that compound. Bevan et al. is enabled because the promoter function of SEQ ID NO :4 is an inherent property of the nucleotide sequence itself. Since the nucleotide sequence taught by Bevan et al. includes the complete nucleotide sequence of SEQ ID NO:4, Bevan et al anticipates the claimed invention.

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Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

Cynthia Collins 3/29/04